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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,430	03/01/2004	Carl Frederick Behr	38-21(52258)C	9938
27161	7590	02/23/2006	EXAMINER	
MONSANTO COMPANY 800 N. LINDBERGH BLVD. ATTENTION: GAIL P. WUELLNER, IP PARALEGAL, (E2NA) ST. LOUIS, MO 63167			CHUNDURU, SURYAPRABHA	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/790,430	Applicant(s) BEHR ET AL.	
	Examiner Suryaprabha Chunduru	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,13 and 16-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,13,18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 4, 2005 has been entered.

Status of the Application

2. The action is in response to the RCE filed on November 4, 2005. Currently claims 7, 13, 16-19 are pending. Claims 13, 16 are amended. Claims 1-6, 8-12, 14-15 are cancelled. All arguments and amendment have been fully considered and thoroughly reviewed and deemed persuasive in view of the amendment.

Priority

3. This application filed on March 01, 2004 is a DIV of 09/872,051 filed on 6/1/2001, now PAT 6,825,400.

New Grounds of Rejections

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

A. Claims 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Sigma Catalog (Molecular biology Products, oligonucleotides, page 1565, 1997).

Sigma Catalog teaches hexanucleotide sequence containing all possible sequences (see page 1565) that are equivalent with the claimed DNA molecules of Claim 13, that recites DNA molecule comprising “a nucleotide sequence selected from the group consisting of SEQ ID NO. 9, SEQ ID No. 10 and SEQ ID NO. 12 and complements thereof” . Since the claimed DNA sequences are within the pool of hexamers or hexanucleotides there is a subset which would function as sequences as claimed. Since the claims recite a nucleotide sequence”, which is treated as having fragments readable on any of the hexamers sequences.

B. Claims 16-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Barry et al. (USPN. 6,448,476).

Note: According to MPEP 2114, A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). Further MPEP 2112.01 states “Products of identical chemical composition can not have mutually exclusive properties.” A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Thus the preamble reciting a diagnostic kit for corn event PV-ZMGT32(nk603) and its progeny is an intended use and is not given any patentable weight. Since the prior art teach a kit

comprising a DNA molecule with sufficient length as claimed in the instant claim 16 meets the structural limitations of the instant claims.

Barry et al. also teach a kit of claim 16 comprising DNA molecules (see col. 7, line 1-10). Barry et al. teach a DNA molecule of sufficient length of contiguous nucleotides of claim 16, wherein said DNA molecule being homologous or complementary to nucleotides of SEQ ID No. 8 (see sequence alignment for a sufficient length of contiguous nucleotides (202 -1 of SEQ ID No. 27) homologous to the position 163-364 of SEQ ID No. 8)).

With regard to claim 17-19, Barry et al. teach that the pair of DNA molecules are at least 18-30 nucleotides in length (see sequence alignment for a sufficient length (1-202 nucleotides in length) of contiguous nucleotides of SEQ ID No. 8 (position 163-364) with a fragment position 202-1 of SEQ ID NO. 27).

Thus the disclosure of Barry et al. meets the limitations in the instant claims.

The following rejections are made based on the phrase “complements thereof” which is given the broadest reasonable interpretation as fragments of the claimed DNA molecules, because the recitation of the phrase “thereof”.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barry et al. (USPN. 6,448,476) in view of Strittmatter et al. (Nucleic Acids Res., Vol. 12, pp 7633-7647, 1984, Accession No. X 86563) and Buck et al. (Biotechniques, Vol. 27, No. 3, page 528-536, 1999).

Barry et al. teach a DNA molecule comprising a DNA sequence homologous to nucleotide positions between 305 and 498 of the claimed SEQ ID No. 7 (see the sequence alignment of SEQ ID No. 27 (positions 1-101) of patent 6,448,476 homologous or complementary to nucleotide position 325-425 of SEQ ID No. 7).

However Barry et al. did not teach a DNA sequence or complement thereof, having at least 11 nucleotides in length, homologous or complementary to nucleotides 1-304 of the claimed SEQ ID NO.7 and use of said DNA molecules as primers or probes.

Strittmatter et al. teach a complete genomic sequence (accession No. X86563) that comprises a sufficient length of nucleotides homologous to positions between 1-304 of SEQ ID No. 7 (see sequence alignment from blast search indicating sequence alignments for 1-11 nucleotides of SEQ ID No. 7 with nucleotide position 73754-73764 of Zea mays genomic sequence).

Buck et al. disclose design strategies and performance of custom made primer submissions from a number of labs (39) (page 532, column 3), with 69 different primers being submitted (see page 530, column 1). Buck also tested 95 primers spaced at 3 nucleotide intervals along the entire sequence at issue, thereby testing more than 1/3 of all possible 18 mer primers on the 300 base pair sequence (see page 530, column 1). When Buck tested each of the primers selected by the methods of the different labs, Buck found that EVERY SINGLE PRIMER worked (see page 533, column 1). Only one primer ever failed, No. 8, and that primer functioned when repeated. Further, EVERY SINGLE CONTROL PRIMER functioned as well (see page 533, column 1).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to use the known sequences as taught by Barry et al. with a DNA sequence as taught by Strimatter et al. and a step to generating primers and primer pairs to amplify a target nucleotide sequence designed based on known target sequences because Barry et al. teach a known sequence of an insert DNA molecule having at least 11 contiguous sequences and Strittmatter et al. teach a DNA molecule of maize genome to form a pair of DNA molecules. Buck et al. further supports the obviousness of generating primers, wherein Buck provides a direct evidence that all primers having about 30 nucleotides in length would be expected to function, and in particular, all primers selected according to the ordinary criteria, however different, are used by different laboratories. It is particularly striking that all 95 control primers functioned, which represent 1/3 of all possible primers in the target region. This clearly shows that every primer would have a reasonable expectation of success. In the recent court decision *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the court determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding

structural or functional homologs, however, the court stated "Normally, a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. Since the claimed product involves known sequences as taught by Barry et al. and Strittmatter et al. they simply represent structural homologs of the known DNA sequences and generating primers or probes from known sequences as taught by Buck et al. and is *prima facie* obvious over the cited references in the absence of secondary considerations. The ordinary artisan would have been motivated to generate a number of primers probes for diagnostic purposes from known sequences as exemplified by Barry et al. and Strittmatter, and such structural homologs used as primers or probes are considered functionally equivalent to the claimed DNA molecules in the absence of secondary considerations.

Response to Arguments:

6. Applicants' arguments and amendment are fully considered and found persuasive in part.
7. With regard to the rejection under 35 USC 112, second paragraph, Applicants' amendment and arguments are fully considered and the amendment to claim 13 is not persuasive. The claim recites "a nucleotide sequence" which is considered as fragments of sequences having said sequences. Amendment to recite "the nucleotide sequence" would obviate the rejection. The rejection is maintained herein since the amendment reads any nucleotide fragment thereof.
8. With regard to the rejection made under 35 USC 102(e) to claim 7, 16-19 as being anticipated by Barry et al. Applicants' arguments and amendment are fully considered and found persuasive in part. Applicants arguments regarding claim 7 have been found persuasive, However Barry et

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al. anticipates the claims 16-19. The rejection is re-written to address the limitation in claims 16-19 as above.

9. With regard to the rejection under 35 USC 102(b) to claim 13, as being anticipated by Marra et al., Applicants' amendment and arguments have been considered and the rejection is withdrawn herein in view of the amendment deleting SEQ ID No. 11.

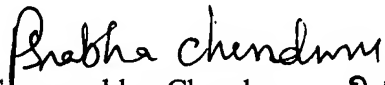
Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Suryaprabha Chunduru 2/17/06
Patent Examiner
Art Unit 1637